Remarks/Arguments

Applicants have received and carefully reviewed the Office Action of the Examiner mailed April 17, 2008. Currently, claims 38-58 remain pending. Claims 38-58 have been rejected. Favorable consideration of the following remarks is respectfully requested.

As an aside, it should be noted that reference numeral 70, referred to by the Examiner in the §102/103 rejections, does not appear in Figure 4 of Gibbs, nor does it appear in any of the other Figures therein. Clarification of the Examiner's intent in a further non-final reply would be appreciated.

Claim Rejections – 35 USC § 102

Claims 38-58 were rejected under 35 U.S.C. 102(b) as anticipated by Gibbs et al. (U.S. Patent No. 5,330,482), hereinafter Gibbs. After careful review, Applicant must respectfully traverse this rejection.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, *814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). (See MPEP § 2131).* Nowhere does Gibbs appear to teach or suggest, "body including a cold formed nickel-titanium alloy having a transformation temperature greater than a mammalian body temperature, wherein the nickel-titanium alloy exhibits linear pseudoelasticity regardless of stress applied to the body", as recited in claim 1.

Instead, Gibbs appears to teach a device having an unspecified transformation temperatures and unspecified initial and final mechanical characteristics other than to note that "after heat is applied" the material has some degree of shape memory. As described by Gibbs, the initial state might be that of a shape memory material and the "heat treatment" might be at any temperature which allows some degree of shape memory to remain, for example a 1 degree temperature increase incidental to soldering would suffice to satisfy the heat application teaching of Gibbs without producing the "cold formed" article posited by the Examiner. Additionally, the Examiner has asserted "that the device of Gibbs et al is not heat treated until *after* the basket portion has already been formed". (Emphasis provided by the Examiner.) Assuming, as the Examiner apparently does without support, that the device of Gibbs is formed from the commonly available wire stock, the wire has certainly been "heat treated" at least during the formation of the ingot from which the wire was drawn and prior to the heat treatment of Gibbs. Gibbs only specifies that the wire basket "has been formed" without indicating that cold working has occurred. The word "cold" does not appear in Gibbs and there does not appear to be sufficient detail provided regarding the "forming" operation to justify the application of the term of art "cold working" to that operation. Simple flexing of the nitinol wire may suffice to "form the basket" prior to a heat application step suggested by Gibbs. While Gibbs appears to specify a nominal composition of "about 55% Ni and 44% Ti", this is insufficient to specify the associated A_s and/or A_f transition temperatures. Indeed, compositions having this ratio may be produced which are amorphous and therefore lack the martensite and/or austenite phases required to have the requisite phase transitions before adequate annealing. Examination of product specification literature for nitinol alloys comprising 56% Ni (about 55%) indicate a range, upon heating, of -30 to -15 °C in the observed A_s and -10 to 20 °C in the observed A_f with each of the transitions clearly lying below 37 °C. A second 56% Ni nitinol alloy is specified as having a range of properties, upon heating, of -15 to -15 °C in the observed A_s and 15 to 30 °C in the observed A_f with each of the transitions clearly lying below 37 °C. It would be understood by one of ordinary skill in the art that the nitinol transition temperatures in question are highly dependent upon both composition and thermal history and that the information provided by Gibbs is insufficient to anticipate the pending claims. Indeed, a nitinol ingot, from which wire is commonly formed, is said to have a distribution of transformation temperatures along the ingot. For at least these reasons, Gibbs fails to provide *each and every element as set forth in the claim* and Applicant respectfully requests that the rejection of claim 1 be withdrawn.

Nowhere does Gibbs appear to teach or suggest, "the body including a cold formed nickel-titanium alloy, wherein the nickel-titanium alloy is in a martensitic phase when the body is stressed into a first shape and when the body is stress relieved to a second shape, and wherein the nickel-titanium alloy has a transformation temperature >37 degrees C", as recited in claim 47. As discussed above, Gibbs does not appear to disclose or teach either cold forming or nitinol transition temperatures, A_s and/or A_f greater than 37 °C. Further, Gibbs does not include the words "martinsite" or "martensitic" and so cannot teach or disclose an alloy in a martensitic phase at any stage of his process, whether before or after heat treatment, unless it can be shown that every alloy composition, including the known amorphous nitinol materials, "composed of about 55% Ni and 44% Ti, with trace elements of Cu (150 ppm), Fe (110 ppm), and Mn (21 ppm)" inherently includes a martensitic phase regardless of its thermal and/or mechanical history.

Nowhere does Gibbs appear to teach or suggest, "providing struts including a cold formed nickel-titanium alloy; setting a transformation temperature >37 degrees C.; cold forming the struts into a body having a shape; stressing the body into a first shape wherein the nickel-titanium alloy is in a martensitic phase", as recited in claim 53. As discussed above, Gibbs does not appear to disclose or teach either cold forming or nitinol transition temperatures, A_s and/or A_f greater than 37 °C. Further, Gibbs does not teach or disclose the presence of a martensitic phase in the stressed body. Accordingly, Gibbs does not appear to anticipate *each and every element as set forth in the claim* and Applicant respectfully requests that the rejection of claim 53 be withdrawn.

Additionally, for similar reasons as well as others, claims 39-46, 48-52, and 54-58, which depend from claims 38, 47, and 53 respectively, and include significant additional limitations, are believed to be not anticipated by Gibbs and Applicants respectfully request that the rejections be withdrawn.

Claim Rejections – 35 USC § 103

Claims 38-58 were rejected under 35 U.S.C. 103(a) as being unpatentable over Gibbs et al. (U.S. Patent No. U.S. Patent No. 5,330,482). After careful review, Applicant must respectfully traverse this rejection.

"All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). (MPEP § 2143.03). As discussed previously, nowhere does Gibbs appear to disclose "body including a cold formed nickel-titanium alloy having a transformation temperature greater than a mammalian body temperature, wherein the nickel-titanium alloy exhibits linear pseudoelasticity regardless of stress applied to the body", "the body including a cold formed nickel-titanium alloy, wherein the nickel-titanium alloy is in a martensitic phase when the body is stressed into a first shape and when the body is stress relieved to a second shape, and wherein the nickel-titanium alloy has a transformation temperature >37 degrees C", or "providing struts including a cold formed nickel-titanium alloy; setting a transformation temperature >37 degrees C.; cold forming the struts into a body having a shape; stressing the body into a first shape wherein the nickel-titanium alloy is in a martensitic phase" as found in pending claims 38, 47, and 53 respectively and discussed in some detail above. Therefore, Gibbs et al. does not appear to teach all the claim limitations, as is required to establish a *prima facie* case of obviousness. Accordingly, for at least the reasons cited, claims 38, 47, and 53 are believed not to be anticipated by Gibbs et al. and Applicant respectfully requests that the rejection of those claims be withdrawn.

Further, if an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). (MPEP 2143.03) Accordingly, claims 39-46, 48-52, and 54-58, which depend from claims 38, 47, and 53 respectively, and include significant additional limitations, are believed to be not anticipated by Gibbs and Applicants respectfully request that the rejections be withdrawn.

The Examiner has asserted, in making a single reference 103(a) rejection, that the device of Gibbs is formed from nickel titanium alloy, as claimed, and accordingly, is considered to comprise the same claimed characteristics. This position is at odds both with the well known properties of nitinol alloys whose characteristics vary greatly depending on their thermal and mechanical history and with the claimed characteristic transition temperatures, A_s and/or A_f greater than 37 °C, which are not common to all nitinol alloys or even to the specific composition of Gibbs absent specified processing not disclosed by Gibbs. Mere selection of a known material composition does not suffice to anticipate the properties in question in the pending claims which result from a subsequent treatment and so the selection of the composition is not an obvious design choice.

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Reexamination and reconsideration are respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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Glenn M. Seager, Reg. No. 36,926
CROMPTON, SEAGER & TUFTE, LLC
1221 Nicollet Avenue, Suite 800
Minneapolis, Minnesota 55403-2420
Tel: (612) 677-9050